REMARKS

Claims 1-15 were originally presented. New claims 16-19 are presented herein. The claims presently under consideration are claims 1-19, as set forth herein. These claims are supported by the specification as filed, and Applicant believes that no new matter has been added. Applicant respectfully requests that the Examiner reconsider and withdraw the various grounds of rejection of the claims.

On page two of the Office Action, the Examiner has acknowledged receipt of Applicant's information disclosure statements filed 6/15/2004, 5/5/2006, and 11/13/2006. However, the Examiner states that these disclosures fail to "comply with 37 CFR 1.98(a)(2) which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed." Applicant encloses herein a subsequent information disclosure statement including all requisite references from the 6/15/2004 filing (non-patent literature). Applicant notes however, that MANDELL, R.B., "Contact Lens Practice: Hard and Flexible Lenses", 2nd ed., Charles C. Thomas, Springfield, vol. 3, 1974 is an 819 page text. Applicant has enclosed within the information disclosure statement a copy of the title page and table of contents for this reference.

On pages 2-4 of the Office Action, the Examiner rejects claims under 35 U.S.C. 112 first paragraph, as not being enabling for "substantially optically transparent". Pursuant to the teleconference of November 15, 2007, Applicant has revised claim 2 to read as follows: "[...] said contact lens remains optically transparent, wherein optically transparent is a degree of transparency equal to that of p-HEMA or other material employed as a contact lens [...]". Applicant notes that to ensure transparency it is

important to minimize particle aggregation as shown through the examples described in [0066]-[0070]. The aggregation can be minimized by minimizing interaction of surfactants (for surfactant based particles) with the monomer as evident from the first three lines of [0068], lines 5-11 of [0069], or by stabilizing the surface of particles as evident from [0070]. A person of ordinary skill could use these approaches to minimize particle aggregation and so ensure transparency. Alternatively, a skilled person can trap particles listed in [0025] – [0052] in lenses by following protocols described in [0059], and then measure transparency by following protocols described in the [0063]. By minimal experimentation, a person having ordinary skill in the art could obtain desired transparency. Applicant further notes that acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. Thus Applicant submits: 1/ enablement is provided for a contact lens having nanoparticles dispersed therein, and enablement is provided for the term "optically transparent".

The Examiner rejects claims 2, 6, 8, 11, and 12 under 35 USC 112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically as to claim 2, the Examiner notes that there is insufficient antecedent basis for the limitation "said lens". The Examiner suggests revising the claim to read "said contact lens". Applicant has amended the claim in line with the Examiner's suggestion thereby rendering this rejection moot.

As to claim 6, the Examiner states that the phrase "such as" renders the claim indefinite as it is unclear whether the limitations following the phrase are part of the

claimed invention. Applicant has amended claim 6 and added new claims 16-19 rendering this rejection moot.

As to claim 8, the Examiner notes that there is insufficient antecedent basis for the limitation "said encapsulation material". Applicant has amended claim 7 thereby rendering this rejection moot.

As to claim 11, the Examiner is unclear as to the meaning of "said ophthalmic drug is substantially saturated aqueous solution of said ophthalmic drug". The Examiner proposes that the following language may be clearer: "said ophthalmic drug is substantially saturated with an aqueous solution of said ophthalmic drug". Applicant has amended the claim in line with the Examiner's suggestion thereby rendering this rejection moot.

As to claim 12, the Examiner notes that there is insufficient antecedent basis for the limitation "kit of claim 12". Applicant has amended claim 12 thereby rendering this rejection moot.

On page 4 of the Office Action the Examiner has rejected claim 12 under 35 U.S.C. 101/112, as being incomplete for omitting essential steps. Applicant submits that the revisions to claim 12 render this rejection moot.

On pages 4-5 of the Office Action the Examiner rejects the claims on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 3-8 and 14 of co-pending Application No. 10/454,836. A terminal disclaimer is attached hereto.

On page 6 of the Office Action, the Examiner has rejected claims under 35 U.S.C. 102(e) as being anticipated by Resnick [US 2002/0141760 A1] (hereinfafter Resnick). However, Applicant submits that the focus and intent of Resnick's invention is very

different from that of the current invention, and that Resnick does not provide enabling data for a person of ordinary skill to load nano/microsphers into contact lenses for the purpose of extended drug delivery. Resnick's disclosure describes loading nano and microspheres into contact lenses to protect ocular tissue from high intensity radiation or repeated exposure to radiation. The properties required in microsphere to accomplish the said objective are high absorption of the radiation. Resnick teaches on various materials that can accomplish this including spheres loaded with Molybdenus disulfide, sulphur, metal oxides, etc. Rensick presents enabling data to prepare contact lenses loaded with such particles so that wearer of such lenses is protected from radiation.

Applicant notes that Resnick refers to drug delivery from these lenses in a very general fashion in paragraph 19. Here Resnick states:

> A further aspect of the invention is a novel chemical or gas delivery system which may be used in combination with the instant system to accomplish levage of the organ (eye) or to treat injuries by application of time-released substances directly onto the surface of the cornea or to the overall suface of the organ (eye), after or prior to injury, or during incidences of battle, for example, or while recovering from eye or facial surgery or injuries. I shall cause the filing of a separate patent application, without traverse, concerning this aspect of the invention, but mention it here, only to document discovery and concept dates as a matter of record.

Applicant submits that the above paragraph is not an enabling disclosure.

- Resnick does not teach on the issue of duration of release. Further Resnick does not provide an enabling disclosure as to either extended delivery or time-release delivery as defined by claim 1. The present invention teaches that contact lenses without particles can load significant amounts of drugs and the purpose of the particles is not to increase loading but to attenuate drug release rates. This concept is not disclosed by Resnick.

- Resnick does not teach that the particles have to be designed specifically for a given drug such that they attenuate the drug release rates from the lens.
- Resnick does not disclose "optically transparent". Applicant submits it would not have been obvious to one of ordinary skill in the art to create transparent matrices that contain particles. Indeed there are several systems with nanoparticles that do not stay optically transparent. Further, Resnick does not disclose optical transparency as being a degree of transparency equal to that of p-HEMA or other material employed as a contact lens as defined by claim 2.
- Resnick does not disclose an amount of nanoparticles from about 1 to about 5%, by weight, based on the weight of the contact lens, as defined by claim 3.
- Resnick does not provide instruction as to the main issues relevant to transparency including particle size, loading and refractive index contrast.
- The sketches in Fig. 1-3 of Resnick show systems that would certainly not be transparent because of the high degree of loading evident in the figures; thus teaching away form the present invention.
- Resnick does not provide an enabling disclosure related to extended delivery or time-release delivery of lidocaine, timolol, ciproflaxin, cyclosporin A, or pilocarpine as defined by claim 6.
- Resnick does not provide an enabling disclosure related to extended delivery or time-release delivery of anti-protozoal drugs, steroids, non-steroid or antibiotics as defined by claim 6.
- Resnick does not provide an enabling disclosure related to nanoencapsulating an ophthalmic drug is with an encapsulation material in an oil-in-water emulsion as defined by claim 7.

- Resnick does not provide disclosure related to encapsulation materials as defined by claim 8.

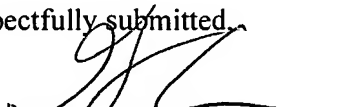
Anticipation requires that each and every element of the claimed invention be disclosed in a single reference. Further, to anticipate, the identical subject matter must not only be previously known, but the knowledge must be sufficiently enabling to place the information in the possession of the public. Applicant submits that Resnick does not provide an enabling disclosure.

On pages 7-9, of the Office Action, the Examiner has rejected claims under 35 U.S.C. 103 as being unpatentable over Resnick. Applicant traverses. Unlike the present invention, which is directed to a drug delivery system, Resnick is directed to a means of protecting the eye. Resnick would not enable one of ordinary skill in the art to practice the present invention.

Applicant has earnestly endeavored to place the application in condition for allowance and favorable action toward that end is respectfully requested. The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (C05202-11154US01) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

Date: December 17, 2007

By: 

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